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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/687,336
Filing Date: October 16, 2003
Appellant(s): KILCOYNE ET AL.

Caleb Pollack
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/14/2012 appealing from the Office action mailed 8/8/2011.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:
Claims 50-60.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

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subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

Anggiansah et al (Primary Peristalsis is the Major Acid Clearance Mechanism in Reflux Patients); Gut 1994; 35: 1536-1542.

Johnsson et al (Determinants of Gastroesophageal Reflux and their Inter-relationships).

Br. J. Surg., Vol.76, No.3, March 1985, p.241-244.

5984875	Brune	11-1999
6416471	Kumar et al	07-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. **Claims 50-51 and 58-60** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anggiansah et al (Primary Peristalsis is the Major Acid Clearance Mechanism in Reflux Patients) in view of Johnsson et al (Determinants of Gastroesophageal Reflux and their Inter-relationships).

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2. In regards to **Claim 50**, Anggiansah et al disclose a system for measuring physiological parameters in the body of a patient indicative of gastroesophageal reflux, the system comprising:

a monitoring device (pH catheter and pressure sensing catheter – p.1537 especially “pH measuring assembly” in right column), said monitoring device comprising a housing adapted to be implanted in the body of a patient by attachment to tissue inside the body (using micropore tape – p.1537 left column), wherein www.dictionary.com defines implant as “inserted into the body,” and a plurality of sensors (6 pressure transducers and pH electrode – p.1537 right and left column) included in said housing, wherein each of the plurality of sensors is capable of independently measuring a different respective physiological parameter indicative of gastroesophageal reflux, i.e. pH and pressure, and wherein said monitoring device periodically transmits a signal indicative of the value of the respective physiological parameter measured by each of the plurality of sensors (monitoring at 8 samples/s – p.1537);

a receiver (recording device – p.1537 right column bottom) that receives the signals from the monitoring device, said signals representing measurements made by the respective plurality of sensors, monitors the physiological parameters indicative of gastroesophageal reflux based on at least the received pH signals, and is capable of determining at least the presence of gastroesophageal reflux based on said plurality of signals (p.1537 – left column).

3. However, Anggiansah et al do not expressly disclose that the determination of gastroesophageal reflux is based upon both the pH and pressure signals. Johnsson et al teach that pressure data is highly valuable in gastroesophageal reflux determination and is

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the single variable that correlates most strongly to the amount of reflux determined using at least pH monitoring, see at least abst, Table 1, first page left column. Anggiansah et al teach all the structural elements of the claimed invention except an express recitation of the determination of the gastroesophageal reflux is based upon both the pH and pressure signals. Since Johnsson et al teach that pressure data is so highly valuable in the determination of gastroesophageal reflux, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the determination of gastroesophageal reflux performed by Anggiansah et al be made with both pH and pressure signals, thus providing a recitation of the determination based upon each of said plurality of signals received from said plurality of sensors (pH and pressure) as suggested by Johnsson et al, to more accurately determine the presence and amount of gastroesophageal reflux in the patient due to a known correlation between pressure, pH, and reflux.

4. In regards to **Claim 51**, Anggiansah et al disclose at least one of said plurality of sensors includes a pH monitor (p.1537).

5. In regards to **Claim 58**, Anggiansah et al disclose the receiver (recording device) monitors a change in pH as a function of distance from a lower esophageal sphincter (p.1537 – left column).

6. In regards to **Claim 59**, Anggiansah et al in combination with Johnsson et al disclose said plurality of sensors include a pH monitor and an auxiliary sensor, wherein

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said auxiliary sensor is to measure an auxiliary physiological parameter that is not a pH parameter, i.e. pressure, wherein the receiver is configured and thus capable of receiving a pH reading from said pH sensor and to adjust said pH reading based on the measured value of the physiological parameter, see Figure 4 (p.1538-1542 – Anggiansah et al). Also see correlation of Johnsson et al.

7. In regards to **Claim 60**, Anggiansah et al disclose the auxiliary physiological parameter is selected from the group consisting of: an ion concentration, a temperature, and a pressure (p.1573 – left column).

8. **Claims 52-55** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anggiansah et al in view of Johnsson et al, further in view of Brune (US Pat No. 5984875).

9. In regards to **Claim 52**, Anggiansah et al as modified by Johnsson et al above disclose the plurality of sensors includes a pH monitor (Col.4: 64) but do not explicitly disclose said sensors include an RF transmitter and a microprocessor. Brune teaches the use of an RF transmitter 9,10 to transmit the signals from an analogous implanted sensor 2 (Col.6: 40-42). Brune also teaches analogous implanted sensor 2 includes a microprocessor 7 that periodically receives a signal from the sensor and induces the RF transmitter to periodically send an RF signal indicative of the sensor (Col.6: 22-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time the

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invention was made to modify the invention of Anggiansah et al as modified by Johnsson et al so that the plurality of sensors include an RF monitor as an effective means to transmit the signal information wirelessly. Also, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the plurality of sensors of Anggiansah et al as modified by Johnsson et al and Brune to include a microprocessor that periodically receives a signal from the pH monitor and induces the RF transmitter to periodically send an RF signal indicative of the pH measured by the pH monitor as an effective means to periodically transmit the pH information signal.

10. In regard to **Claims 53-54**, Anggiansah et al as modified by Johnsson et al above and in combination with Brune disclose the plurality of sensors each with a microprocessor above but do not explicitly disclose the microprocessor enables the pH monitor during a first interval and then disables the pH monitor during a second interval, while the RF transmitter is enabled during the second interval and disabled during periods of each cycle other than the second interval. However, Brune does disclose a first interval which is defined as when the microprocessor 7 periodically enables the sensor to obtain a signal and a second interval which is defined as when the RF transmitter 9,10 is enabled to transmit the signal (Col.6: 35-42). Brune also teaches that battery life is conserved by disabling the respective functions i.e. keeping the sensor in sleeping mode until it is necessary to trigger the signals (Col.6: 32-35).

11. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Anggiansah et al as modified by Johnsson et al and Brune such that during the first interval the RF transmitter is disabled

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and during the second interval the pH monitor is disabled, wherein the disabling occurs when the respective function is not performed, i.e. the pH monitor of the respective sensor is disabled during periods of each cycle other than the first interval and the RF transmitter is disabled during periods of each cycle other than the second interval, as an effective way to enhance the battery life conservation by only enabling the proper function as it is being used and disabling it during all other times.

12. In regards to **Claim 55**, Anggiansah et al as modified by Johnsson et al above disclose the invention above but do not disclose each signal transmitted by the plurality of sensors includes an identifier that is indicative of the sensor from which the signal is sent. Brune et al disclose an analogous measuring system comprising sensors 2 that transmit a signal including an identifier code that is indicative of the sensor from which the signal is sent (Col.5: 49-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the signals sent from the implanted sensors of Anggiansah et al as modified by Johnsson et al an identifier code as taught by Brune to effectively differentiate the particular sensor from which each signal was sent.

13. **Claims 56-57** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anggiansah et al in view of Johnsson et al and Brune, further in view of Kumar et al (US Pat No. 6416471).

14. Anggiansah et al as modified by Johnsson et al and Brune above disclose the receiver (recording device) includes circuitry to sense the position of the patient and

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periodically records the position of the patient (p.1538 – right column – Anggiansah et al). However, Anggiansah et al in combination with Johnsson et al and Brune do not disclose the receiver worn by the patient. Kumar et al disclose an analogous receiver 20 worn by the patient best seen in Figure 1 as well as circuitry to sense a position of the patient (Col.11: 35-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the receiver of Anggiansah et al as modified by Johnsson et al and Brune to be worn by the patient as taught by Kumar et al for ease of transportation and monitoring without hindering patient activity.

(10) Response to Argument

15. Appellant contends that Anggiansah and Johnsson do not teach determining gastroesophageal reflux based on pH and pressure, because at least Johnsson teaches that *an amount* of reflux is dependent upon pressure, but not *a presence* of reflux. It is submitted that the teaching of an amount of reflux constitutes a presence of reflux because a presence of must include an amount, and thus, Anggiansah and Johnsson do teach a presence of reflux. Appellant also appears to argue that the teachings of Johnsson would not be relevant to that of Anggiansah because while Johnsson is directed towards a study of a distal esophageal high pressure zone, Anggiansah is directed towards a study of reflux in various locations in the esophagus. However, this is not found persuasive because it is clear that Johnsson constitutes analogous art as pertaining at least to appellant's problem solving area, i.e. detection of reflux, as well as field of endeavor. It is noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the

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claimed invention must be expressly suggested in any one or all of the references.

Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

16. Appellant also contends that Anggiansah does not teach the device “implanted...by attachment to tissue inside the body” because the catheters inserted into the esophagus of the patient are not “firmly fixed.” However, as acknowledged by appellant in the Brief, a broad and reasonable definition of “implant” includes “to insert into the body” (from www.dictionary.com). This definition when applied to the catheters of Anggiansah clearly shows the device implanted, i.e. inserted, into the body.

17. Furthermore, the insertion of the device into the esophagus is fully capable of “attachment” to tissue inside the body, i.e. in the throat or even into an incision/cavity of the patient, due to the lack of a positive recitation of the attachment structure. The functional language recitation in the claim only requires that the device be “adapted” for attachment to tissue inside the body, i.e. be capable of. Moreover, this does not include the tape that has been disclosed to also secure the catheter, which even if placed outside the body nevertheless causes indirect, if not direct, “attachment to tissue inside the body” of the patient. It is noted that the claims neither recite that the *entire* device is implanted inside the body nor the mechanism of attachment.

18. Lastly, appellant contends that the two bonded catheters of Anggiansah do not constitute a plurality of sensors included in “a housing” because the two catheters are separate. It is submitted that both the pressure and pH catheters *as bonded together* constitute a housing as defined above, in which said sensors are included. The term

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“housing” is not necessarily limited to a single integral element. Furthermore, the sensors of Anggiansah are necessarily “included in” said catheters, as claimed.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner’s answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/H. N./

Examiner, Art Unit 3736

Conferees:

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736

/THOMAS J SWEET/

Supervisory Patent Examiner, Art Unit 3738